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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,191	10/22/2003	Pamela Cifra	13720-105089US1	8424

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/692,191	CIFRA ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,30,31,33-67,73,76-99,105-109 and 111-125* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,24-27,33-35,99,105-108,114-117,119-121 and 123-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/18/07,09/25/07&01/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2-23,28,30,31,33-67,73,76-98,109,111-113,118 and 122.

DETAILED ACTION

Claims 1-28, 30-31, 33-67, 73, 76-99, 105-109 and 111-125 are presented for examination.

Applicant's Amendment filed December 17, 2007 has been received and entered into the present application. Applicant's Information Disclosure Statements (IDS) filed September 18, 2007 (two pages), September 25, 2007 (two pages) and January 21, 2008 (one page) have each been received and entered into the present application. As reflected by the attached, completed copies of form PTO/SB/08(a-b) (five pages total), the Examiner has considered the cited references.

Claims 1-28, 30-31, 33-67, 73, 76-99, 105-109 and 111-125 are pending. Claims 2-23, 28, 30-31, 33-67, 73, 76-98, 109, 111-113, 118 and 122 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 1, 24-27, 33-35, 99, 105-108, 114-117, 119-121 and 123-125 remain under examination. Claims 123 and 125 are amended.

Applicant's arguments, filed December 17, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Request for Examination of Claims 28, 109 and 113

Applicant requests examination of withdrawn claims 28, 109 and 113, noting that MPEP §806.04 states that, "an allowable generic claim may link a reasonable number of species embraced thereby". Applicant alleges that the Examiner erroneously takes the position that one specie is the maximum reasonable number of species for examination and asserts that such a position is inconsistent with the MPEP and 37 C.F.R. 1.146, which provides for the examination of a "reasonable number" of species.

Applicant's request has been fully and carefully considered, but is respectfully denied. Applicant is reminded that he was required to, and did specifically elect, the single disclosed species of zinc citrate

as the zinc-containing compound for examination. Prosecution of the claims was performed to the extent that they read upon the elected species of zinc citrate, which prompted the appropriate withdrawal of claims 28, 109 and 113 from examination due to the fact that each is directed to *non-elected subject matter*.

Applicant is reminded that he is only entitled to examination of additional species outside of the specific species elected for examination *when the generic claim is found allowable*. Please see 37 C.F.R. 1.141(a). In the instant case, the instant generic claims were not found to be allowable due to the rejection(s) over the elected species of zinc citrate. For this reason, the generic claim is not allowable and, thus, Applicant is not entitled to examination of additional species. Furthermore, 37 C.F.R. 1.146 supports this requirement because it clearly provides for requiring Applicant to elect a species of his or her invention to which his or her claims will be restricted if *no claim to the genus is found to be allowable*. As stated *supra*, Applicant's generic claim to "zinc-containing compounds" is *not allowable*, and, therefore, examination is not extended to additional species.

Accordingly, Applicant's request for examination of claims 28, 109 and 113 is clearly not proper at this time and is denied for the reasons explained *supra*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 24-27, 33-35, 99, 105-108, 114-117, 119-121 and 123-125 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (U.S. Patent No. 6,573,299; Issued June 2003, Filed September 1999) in view of Uitto ("Connective Tissue Biochemistry of the Aging Dermis. Age-Related Alterations in Collagen and Elastin", *Dermatol Clin*, 1986 Jul; 4(3):433-436; Abstract Only), each already of record, for the reasons of record set forth at pages 3-11 of the previous Office Action dated June 15, 2007, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Petrus teaches away from the claimed zinc concentration ranges because the reference fails to recognize that zinc compounds can cause skin irritation. Applicant alleges that the fact that Petrus teaches the zinc compounds as being "anti-inflammatory", "virtually non-toxic" and a "potent inhibitor of nitric oxide synthase (NOS)" clearly would motivate the artisan to increase the amount of zinc used in preparing a composition for the aging eye. Applicant further submits that Petrus suggests the use of topical zinc dosages of from 10-20 mg/day, which is much higher than the ranges recited in Applicant's claims. Applicant additionally alleges that the cited combination of references fails to teach or suggest the zinc concentration range(s) of the claimed invention, and relies upon the fact that Petrus discloses several alternatives to zinc for treating the aging eye and fails to provide a teaching or suggestion to favor zinc compounds over any of the other disclosed compounds for treating wrinkles, inflammation, or suppressing NOS expression. Still further, Applicant states that high zinc concentrations were demonstrated in Example 9 to induce elastase activity, which

would break down elastin and defeat the objective of the invention. Once again, Applicant relies upon the evidence provided in Tables 1-4, as set forth in Examples 2-4, to show that high zinc concentrations can lead to irritation and sloughing and that the claimed ranges provide unexpected results. In addition, Applicant asserts that the line of zinc-based commercial products covered by the present claims (i.e., known as RELASTIN) has enjoyed considerable industry recognition and has won a "Best of Beauty" Award for antiwrinkle eye creams following independent testing against other commercial products.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Initially, Applicant alleges that the fact that Petrus teaches that zinc compounds are "anti-inflammatory", "virtually non-toxic" and a "potent inhibitor of nitric oxide synthase" is clear motivation to increase the amount of zinc used and that, given the irritation and sloughing that is known to occur with high zinc concentrations, this teaches away from using the lower amounts of zinc as instantly claimed. However, it is first noted that Applicant is inferring a conclusion from the reference that is not explicitly, or even implicitly, stated in the disclosure of Petrus. Contrary to Applicant's allegations, Petrus clearly and explicitly contemplates variation in the dosage amount of the active zinc component to be used. Please see col.6, l.56-60, which states, "The concentration of the bio-affecting agents [i.e., in this case, zinc citrate] in the composition can also vary greatly and will be dependent upon many factors, e.g., type, bioavailability, potency, surface area to which it is applied, composition used and the amount of the penetrating agent used." This clearly supports the concept of *variation* in the dosage amount and fails to support Applicant's interpretation that the disclosure only provides a reason to increase the dosage amount.

Further, Applicant provides no other support (i.e., evidence, citation of a portion of the reference that supports this interpretation, etc.) for this allegation aside from the assertion that, since zinc is taught by Petrus to have anti-inflammatory and NOS-inhibiting effects and is disclosed as being "virtually non-toxic", one of skill in the art would only be motivated to increase the amount to capitalize on such effects.

However, the idea that the artisan would only be motivated to increase the dosage amount of the active zinc compound based upon the anti-inflammatory and nitric oxide synthase-inhibiting effects is disputed in light of standard medical practice. It is well accepted in the medical and pharmaceutical arts that all pharmacologic therapies have contraindications and/or possible side effects depending on, e.g., the amount used, duration and frequency of use, etc. In view of these facts, the idea that the artisan would have gratuitously increased the effective amount of the active agent just because it has demonstrated a beneficial therapeutic effect at a particular concentration disregards the fact that excessive concentrations of any pharmacologic therapy will result in notable, if not severe and/or fatal, side effects.

For example, aspirin is commonly used as a pain reliever, but high doses in excess of what is therapeutically or medically indicated will result in gastrointestinal bleeding, ulcers, significant prolongation of blood coagulation, hearing loss and/or Reye's syndrome. As a result, one of skill in the art would not have necessarily increased (especially without limit) the dose used to exploit these pain-relieving effects because the pain relief is accompanied by significant (and possibly detrimental) side effects. In other words, though an agent may show benefit to a patient at a reasonable and virtually non-toxic concentration, such properties would not be necessarily suggestive of using the same compound at higher concentrations without the expectation of adverse effects. Accordingly, in view of this knowledge, Applicant's argument that the artisan would only have been motivated to increase the dosage amount of the zinc component as disclosed by Petrus is unpersuasive.

The attempt to patentably distinguish the instantly claimed invention over that of Petrus by alleging that Petrus only discloses topical zinc concentrations of from 10-20 mg/day is also unpersuasive. First, Petrus discloses the use of 10-20 mg/day of zinc for topical application as a *suggested* topical dose of the active agent to achieve the same therapeutic benefit as a comparable oral dosage of the same agent. Applicant is reminded that the disclosure of exemplary embodiments fails to limit the content of a reference solely to what is exemplified. This is because the disclosure of a reference must be considered

as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not limited to that which is preferred and/or exemplified. Please see MPEP at §2123, which states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments…Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." In the instant case, the fact that Petrus explicitly and unequivocally states that the concentration of the bio-affecting agent (i.e., zinc citrate) will vary greatly and will depend upon many factors, such as, but not limited to, the type of agent, bioavailability, potency, surface area to be treated and the amount of penetration enhancer used, is an express acknowledgement that the therapeutically effective amount of the active agent will vary and the determination of the appropriate dosage was well within the skill of the artisan and would not have required undue experimentation.

Second, Petrus discloses that the concentration of the bioaffecting agent will vary from about 0.1-40% of the total composition (col.6, l.60-62). In an effort to demonstrate patentable distinction of the instant claims over that of Petrus with regard to the effective amount used in Applicant's papers filed March 30, 2007, Applicant calculated the molarity of zinc present in the exemplary composition of Examples 1 or 2, which uses 2.0% zinc lineolate. Applicant determined that the zinc compound was present in an amount of 58 mM [i.e., 2% zinc lineolate=2g zinc lineolate/100 ml of composition; (2g zinc lineolate/100 ml of composition)*(1 mol/344g/mol)*(1000 ml/L) = 0.058 M = 58 mM)], which Applicant alleges is much higher than the concentrations that are claimed.

However, as noted *supra*, Petrus is not limited to what is disclosed in the Examples, but rather may be relied upon for all that it would have suggested to one of ordinary skill in the art at the time of the invention. For example, if one were to make the same calculation using a 0.1% concentration of active agent as disclosed by Petrus at col.6, l.60-62, then 0.1% zinc citrate=0.1g zinc citrate/100 ml of composition; (0.1g zinc citrate/100 ml of composition)*(1 mol/574 g/mol)*(1000 ml/L) = 0.0017 M = 1.7

mM=1700 μM (see STN Registry File No. 546-46-3 for molecular formula of zinc citrate). This meets Applicant's claimed concentration ranges of "about 1.0 pM to about 900 μM" (see, e.g., claim 34), "about 100 pM to about 500 μM" (see, e.g., claim 35), "about 1.0 pM to about 10 mM" (see, e.g., claim 99) or "about 1.0 pM to about 1.0 mM" (see, e.g., claim 124) because such a value falls either directly within the claimed range(s) or, in the case(s) where it falls outside the exact range, is still considered to meet the claimed concentration in the absence of an express definition of the term "about" and the degree of variance tolerated, and intended to be conveyed, by this term.

The term "about" permits some tolerance both above and below the recited dosage range(s) absent an explicit definition of the degree of variation intended to be encompassed by the term. Where close prior art exists, the burden is on Applicant to establish that the term "about" is sufficiently clear to avoid such art. In the instant case, Applicant has failed to provide a definition of the term "about" in the instant specification, such that there is no indication or hint as to what amount of variation above or below the recited dosage amount(s) would constitute infringement of the instant claims. There is nothing in the specification, prosecution history or prior art that provides any indication as to what amount of variation is tolerated by the term "about". Absent such information, and further in view of what is actually disclosed by Petrus (i.e., a dosage amount that clearly meets the claimed ranges when using, e.g., 0.1% zinc citrate), Applicant has failed to persuasively distinguish the instant claims over that of the prior art to Petrus.

Applicant additionally appears to be of the persuasion that the disclosure of several alternatives to using zinc as the bio-affecting agent of the composition and a failure to acknowledge zinc as the preferred bio-affecting agent somehow constitutes a teaching away from the use of a zinc compound. This is not persuasive. A preferred or exemplified embodiment does not constitute a teaching away from other embodiments disclosed within the four corners of the reference, including non-preferred embodiments. Applicant is reminded that the disclosure of a reference must be considered as expansively as is

reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not limited to that which is preferred and/or exemplified. Please see MPEP at §2123. Thus, the fact that other compounds may be exemplified or preferred does not negate or direct the artisan away from the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates the use of, a zinc compound (i.e., zinc citrate) as the bio-affecting agent of the disclosed composition.

Still further, Applicant attempts to rely upon Examples provided in the instant specification as evidence of unexpected results and, thus, non-obviousness of the invention over the disclosure to Petrus. Specifically, Applicant relies upon the evidence of Example 9, which demonstrates that high zinc concentrations induce elastase activity and would bread down elastin, as well as Tables 1-4 as set forth in Examples 2-4, to show that high zinc concentrations can lead to irritation and sloughing and that the claimed ranges provide unexpected results.

While the results of Examples 1 and 9 (note that these are the sole examples directed to the increase in elastin concentration) have been carefully and closely considered, it is once again noted that Applicant's experimental data is limited to the use of zinc cation concentrations of between 0.01-0.75 M (i.e., 10 mM-75 mM) to inhibit elastase, whereas the presently claimed subject matter encompasses unspecified, but "elastin-increasing effective amounts" (see, e.g., claim 24), about 1.0 pM to about 900 μM (see, e.g., claim 34), about 100 pM to about 500 μM (see, e.g., claim 35), about 1.0 pM to about 10 mM (see, e.g., claim 99) or about 1.0 pM to about 1.0 mM (see, e.g., claim 124). In other words, the administration of zinc acetate for increasing elastin, where elastase activity is only inhibited in amounts of 0.01-0.75 M, which is equivalent to 10-75 mM, clearly fails to be commensurate in scope with the full scope of ranges presently claimed. Accordingly, the experimental data does not support the concept of non-obvious dosage amounts over the full scope of the presently claimed subject matter, particularly when Petrus (1) teaches amounts that fall within the claimed range(s) and (2) expressly notes that an effective amount of the active agent will necessarily vary depending upon many factors and, therefore,

does not restrict the exemplary amounts taught by the reference.

Further, it remains that the proffered results do not provide a basis for concluding that the claimed subject matter would not have been obvious because the results are limited to zinc cation in the specific range of 0.1-0.75 M, while the claims subject to this rejection encompass the use of zinc citrate in varying amounts of, e.g., "elastin-increasing effective amounts" (see, e.g., claim 24), about 1.0 pM to about 900 μM (see, e.g., claim 34), about 100 pM to about 500 μM (see, e.g., claim 35), about 1.0 pM to about 10 mM (see, e.g., claim 99), or about 1.0 pM to about 1.0 mM (see, e.g., claim 124), that have not been correlated in any way to the amounts tested to show that the experimental data is supportive of the non-obviousness of the full scope of claimed subject matter. Further, it has not been argued or demonstrated on the record that the results obtained with the exemplified combination would have been exemplary of the same or substantially similar results that would have been expected to occur over the entire scope of the claimed subject matter.

In this regard, MPEP §2144.08(II)(B) is relied upon and reads, in-part: "When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the Applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. Id. For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a *prima facie* case of obviousness if a skilled artisan 'could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof.' *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (**Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the**

probative value thereof.) But see, *In re Grasselli*, 713 F.2d at 743, 218 USPQ at 778 (Evidence of superior properties for sodium containing composition insufficient to establish the non-obviousness of broad claims for a catalyst with 'an alkali metal' where it was well known in the catalyst art that different alkali metals were not interchangeable and Applicant had shown unexpected results only for sodium containing materials); *In re Greenfield*, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (Evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way)." (emphasis added)

Here, just as a single point in space fails to define a line, the results demonstrated for the exemplified combination in the exemplified amounts would be insufficient to establish the non-obviousness of the entirety of the presently claimed dosage amounts of the claimed zinc compound (i.e., zinc citrate) absent any concrete evidence or scientifically sound reasoning as to why these other embodiments would have been reasonably expected to demonstrate the same effect. In other words, Applicant has not provided any objective evidence, scientific reasoning or persuasive argument on the record to provide an adequate basis for concluding that exemplary data in the instant specification was somehow probative of the same (or at least substantially similar) effect using the elected subject matter *over the full scope of dosage amounts instantly claimed.* In short, the evidence is, respectfully, insufficient to be supportive of nonobviousness of the claimed dosage amounts.

Moreover, Applicant has failed to compare the instantly claimed invention to that of Petrus in order to support the conclusion that the instantly claimed invention demonstrates unexpected activity over the closest prior art and, thus, distinguishes over the reference. In the absence of a direct comparison with the closest prior art to Petrus to demonstrate that the composition(s) of the prior art would not necessarily possess this same increase in skin elasticity, it is respectfully maintained that the prior art product would

function to achieve this same effect by virtue of the fact that the prior art composition contains the same components in the same amounts as what is instantly claimed (see discussion *supra*) and, thus, would be expected to exhibit the same properties, functions and characteristics as Applicant's composition, absent factual evidence to the contrary. Please note also that *In re Burckel* 592 F.2d 1175, 201 USPQ 67 (CCPA 1979) held that, "An affidavit or declaration under 37 C.F.R. 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness."

Applicant is further reminded that evidence of unexpected properties may be in the form of an indirect comparison of the claimed invention with the closest prior art that is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and MPEP §716.02(d) - §716.02(e). See *In re Blondel*, 499 F.2d 1311, 1317, 182 USPQ 294, 298 (CCPA 1974) and *In re Fouche*, 439 F.2d 1237, 1241-42, 169 USPQ 429, 433 (CCPA 1971) for examples of cases where indirect comparative testing was found sufficient to rebut a *prima facie* case of obviousness. See also MPEP §716.02(b)[R-2](III). However, where the comparison is not identical with the reference disclosure, deviations therefrom should be explained. Applicant is essentially urging the consideration of such results in a vacuum, i.e., without considering what is already disclosed in the prior art, and, accordingly, in view of the fact that Applicant has not provided any explanation as to why a direct comparison with the closest prior art of Petrus was not performed, the alleged evidence of non-obviousness fails to outweigh the evidence of obviousness and is unpersuasive. Without a comparison to the closest prior art, there is no clear basis to conclude that the instantly claimed invention provides unexpected advantages and/or activity over what is already in possession of the public.

Lastly, Applicant's allegation that products within the scope of the instant claims have received "considerable industry recognition" has been considered, but fails to be persuasive for the following reasons: (1) Applicant has failed to describe the specific product formulation that, in fact, has received such recognition and diffusely references "products covered by the present claims", which fails to point

out the specific formulation and (2) the fact that a product covered by the instant claims has been generally received more favorably by consumers than other comparable products does not, without more, support non-obviousness of the invention. Should Applicant be attempting to rely upon evidence of commercial success as indicia of non-obviousness of the claimed invention, Applicant is directed to MPEP §716.03, which requires Applicant to show, *inter alia*, a nexus between the claimed invention and evidence of commercial success, that the evidence of commercial success is, in fact, commensurate in scope with the claimed subject matter, and that commercial success must flow from the functions and advantages disclosed or inherent in the specification description. In the absence of such evidence and/or discussion, Applicant's statements regarding industry recognition of the claimed products are duly noted, but unpersuasive in establishing non-obviousness of the instantly claimed invention over the prior art to Petrus.

For these reasons presented *supra*, and those previously set forth at pages 3-11 of the Office Action dated June 15, 2007, rejection of claims 1, 24-27, 33-35, 99, 105-108, 114-117, 119-121 and 123-125 remains proper and is **maintained**.

Conclusion

Rejection of claims 1, 24-27, 33-35, 99, 105-108, 114-117, 119-121 and 123-125 remains proper and is **maintained**.

Claims 2-23, 28, 30-31, 33-67, 73, 76-98, 109, 111-113, 118 and 122 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614